

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control and Prevention****[30Day-22-1355]****Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) submitted the information collection request titled Phased Approach to the Resumption of Cruise Ship Passenger Operations to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" on April 30, 2021, to obtain comments from the public and affected agencies. This collection accompanies a CDC Order entitled Temporary Extension and Modification of Framework for Conditional Sailing Order (CSO). CDC received twenty (20) comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

## Proposed Project

Phased Approach to the Resumption of Cruise Ship Passenger Operations (OMB Control No. 0920-1335, Exp. 10/31/2021) - Extension - National Center for Emerging Zoonotic and Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) .

### Background and Brief Description

The Temporary Extension and Modification Framework for Conditional Sailing Order (here on referred to as the "CSO Extension") extends The Framework for Conditional Sailing Order published in the *Federal Register* on November 4, 2020, and continues to prohibit a cruise ship operator from commencing or continuing any regular passenger operations without a COVID-19 Conditional Sailing Certificate issued by HHS/CDC. This information collection request outlines the reporting and document retention requirements that are part of a phased approach to resuming passenger operations.

The CSO Extension builds upon the phased-in approach to resume cruise ship passenger operations introduced by the CSO. Cruise ship operators who have already completed the process under the CSO will not have to resubmit any information under the CSO Extension and can continue sailing with passengers without interruption. As many cruise ship operators are now familiar with the CSO and its requirements, many aspects of the

phased-in approach can be completed concurrently under the CSO Extension.

#### Phase 1:

Per CDC's CSO Extension, cruise ships operating or intending to operate in U.S. waters must acknowledge that a complete and accurate COVID-19 response plan (formerly referred to as "No Sail Order (NSO) response plan") is observed. The COVID-19 response plan, which can be submitted by a cruise ship holding company and apply to all cruise ships operated by the holding company's brands, must include: (1) terminology and use of definitions that align with how CDC uses and defines the following terms: "confirmed COVID-19," "COVID-19-like illness," "close contact," "fully vaccinated for COVID-19," and "isolation" and "quarantine" (including timeframes for isolation and quarantine); (2) protocols for on board surveillance of passengers and crew with COVID-19 and COVID-19-like-illness; (3) protocols for training all crew on COVID-19 prevention, mitigation, and response activities; (4) protocols for on board isolation and quarantine, including how to increase capacity in case of an outbreak; (5) protocols for COVID-19 testing that aligns with CDC technical instructions; (6) protocols for onboard medical staffing—including number and type of staff—and equipment in sufficient quantity to provide a hospital level of care (e.g., ventilators, face masks, personal protective equipment) for the infected without the immediate need to rely

on shoreside hospitalization; and (7) procedures for disembarkation of passengers who test positive for COVID-19.

Phase 1 also includes requirements for COVID-19 testing capabilities and reporting for cruise ship operators operating or intending to operate cruise ships in U.S. waters. Cruise ship operators must have onboard testing capabilities to test all symptomatic crew and passengers for COVID-19 and their close contacts. This includes having onboard rapid nucleic acid amplification test (NAAT) point-of-care equipment that meets the requirements specified by CDC in technical instructions or orders and have received CDC approval. For the Phase 1 mass crew testing requirement, cruise ship operators may use an onboard viral test (NAAT or antigen test) or arrange shoreside testing at a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory so long as it meets the requirements specified by CDC in technical instructions or orders and have received CDC approval.

Finally, Phase 1 also includes reporting requirements using the CDC Enhanced Data Collection during COVID-19 Pandemic (EDC) form. In lieu of submitting the Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form for COVID-19-like illness and the Maritime Conveyance Illness or the Death Investigation Form for individual specific cases of COVID-19, the CDC will require daily submission of the EDC form during the period of the CSO Extension. Data points for this form include number of travelers (crew and passengers) currently onboard;

case counts and diagnostic testing data for COVID-19 and COVID-19-like Illness (CLI); screening and testing of asymptomatic travelers, isolation practices, and the percentage of travelers who are fully vaccinated. The data collected in the EDC form are used to inform CDC's COVID-19 Color-Coding System for Cruise Ships. This data will greatly increase the transparency of the overall health of the crew members and passengers, and better allow the CDC to manage potential outbreaks and offer recommendations to the ship and port partners. The color-coding system is only applicable to cruise ships operating or planning to operate in U.S. waters. Status of ships is contingent upon daily submission of the EDC form. When a cruise ship notifies CDC of suspected or confirmed cases of COVID-19 on board, CDC determines whether an investigation is needed based on a predetermined threshold. If an investigation is deemed necessary, CDC will solicit extra information from the cruise ship operator. This investigation gives CDC and the cruise industry the ability to work closely together to protect the health and safety of those on board and in communities.

#### Phase 2A:

The next phase, Phase 2A, focuses on preparation for simulated and restricted voyages. As required under the CSO Extension, a cruise ship operator's agreement with U.S. port authorities and local health authorities must include the following elements: (1) a port agreement between the cruise ship

operator and port authority that takes into consideration the public health response resources of the jurisdiction in the event of a COVID-19 outbreak, a plan and timeline for vaccination of cruise ship crew prior to resuming passenger operations, and vaccination strategies to maximally protect passengers and crew from introduction, amplification, and spread of COVID-19 in the maritime environment and in land-based communities; (2) medical care agreements between the cruise ship operator and health care entities, addressing evacuation and medical transport to onshore hospitals for passengers and crew in need of medical care, in accordance with CDC technical instructions and orders; and (3) housing agreements between the cruise ship operator and one or more shoreside facilities for isolation and quarantine of passengers or crew members with COVID-19 and their close contacts, identified from the day of embarkation through disembarkation for each voyage. Cruise lines/brands may submit these agreements for all the ships in their fleet. Note, these agreements can remain in place for restricted voyages, as long as the agreements remain valid.

In lieu of documenting the approval of all local health authorities of jurisdiction, the cruise ship operator may instead submit to CDC a signed statement from a local health authority, on the health authority's official letterhead, indicating that the health authority has declined to participate in deliberations and/or sign the port agreement (i.e., a "Statement of Non-Participation"). Additionally, the cruise ship

operator may enter into a multi-port agreement (as opposed to a single port agreement) provided that all relevant port and local health authorities (including the state health authorities) are signatories to the agreement.

During discussions with cruise ship operators, port authorities, and state and local health authorities, all parties requested CDC assistance with the required agreements. In response to these requests, CDC has posted specific guidance online and has provided a checklist for additional reference.

#### Phase 2B:

Phase 2B of the CSO Extension establishes the requirements for simulated voyages where volunteers play the role of passengers to test cruise ship operators' ability to mitigate COVID-19 onboard. Passengers on simulated voyages must be at least 12 years old, provide their informed consent, and submit a medical certification to the cruise ship operator prior to embarkation.

Before conducting a simulated voyage, a cruise ship operator must submit a Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate at least five business days prior to the voyage. A cruise ship operator shall not apply for approval to conduct a simulated voyage until all of CDC's requirements relating to onboard laboratory capacity and screening testing of crew in U.S. waters have been satisfied.



A simulated voyage must include the following simulated activities: (1) embarkation and disembarkation procedures, including terminal check-in, (2) on board activities, including at dining and entertainment venues, (3) private island shore excursions, if any are planned during restricted passenger voyages, (4) evacuation procedures, (5) transfer of symptomatic passengers or crew, or those who test positive for SARS-CoV-2, from cabins to isolation rooms, (6) quarantine of all remaining passengers and non-essential crew, and (7) other activities as may be listed in CDC technical instructions and orders.

Additionally, the cruise ship operator must: (1) meet standards for hand hygiene, facemasks, and physical distancing for passengers and crew, as well as ship sanitation, as may be required by CDC technical instructions or orders, (2) conduct laboratory testing of all passengers and crew on the day of embarkation and the day of disembarkation as required by CDC technical instructions or orders, and (3) immediately conduct laboratory testing of any passengers and crew who report illness consistent with COVID-19 during the simulated voyage with rapid point-of-care results as required by CDC technical instructions or orders. Note, CDC may require the cruise ship operator to immediately end the simulated voyage and take other action to protect the health and safety of volunteer passengers and crew if during the simulation a threshold of COVID-19 cases, as determined by CDC in technical instructions, is met or exceeded.

During simulated voyages, the cruise ships are subject to virtual and in-person inspections by CDC. The cruise ship operator's properties and records must be made available for inspection to allow CDC to ascertain compliance with its requirements. Such properties and records include but are not limited to vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, laboratory test results, and employee and passenger health records. CDC has issued additional technical guidance outlining the specific areas that may be inspected and corresponding recommendations. Following each simulated voyage, the cruise ship operator must document any deficiencies in its health and safety protocols through a Simulated Voyage After-Action Report and address how the cruise ship operator intends to address those deficiencies. This After-Action Report must also include COVID-19 test results for any volunteer passengers or crew on the simulated voyage. The After-Action Report must be submitted to the CDC as soon as practicable at the end of the simulation and as part of the cruise ship operator's application for a COVID-19 Conditional Sailing Certificate.

In lieu of conducting a simulated voyage, a cruise ship operator's responsible officials, at their discretion, may sign and submit to CDC an acknowledgement that 95% of crew (excluding any newly embarking crew in quarantine) are fully vaccinated and submit to CDC a clear and specific vaccination plan and timeline to limit cruise ship sailings to 95% of passengers who have been

verified by the cruise ship operator as fully vaccinated prior to sailing.

Furthermore, cruise ships that have been operating restricted passenger voyages under an Acknowledgement by a Cruise Ship Operator In Lieu of a Simulated Voyage may, at their discretion, transition to operating restricted passenger voyages with less than 95% of passengers fully vaccinated without first conducting a simulated voyage if the following are met: (1) The ship must maintain a percentage of fully vaccinated crew that is greater than or equal to 95%. 2) The ship must have operated on restricted passenger voyages under an acknowledgement by the cruise ship operator's responsible officials that they will only operate with 95% of crew (excluding any newly embarking crew in quarantine) and 95% of passengers who are fully vaccinated for at least 60 days. 3) At least 14 days prior to the transition to voyages with less than 95% of passengers fully vaccinated, the cruise ship operator must submit the following to CDC: (1) Protocols for how dining and entertainment venues, and recreational activities including buffets, seated dining, bars (including between bartenders and patrons), theaters, other performance venues, casinos, arcade room, spa services, fitness classes/gymnasiums, muster drills, and other areas where passengers congregate will be modified to incorporate mask use, physical distancing, and other public health measures as outlined in CDC technical instructions. (2) Plans for training crew on new procedures for mask use, physical distancing, and

other public health measures as outlined in CDC technical instructions. (3) Protocols for increasing the number of isolation and quarantine cabins and on-board support staff (e.g., administrative personnel, testing personnel, contact tracers, medical personnel) as determined by the cruise ship operator and as needed in the event of an outbreak. (4) Procedures for how crew will identify and distinguish between passengers who are fully vaccinated and passengers who are not fully vaccinated. (5) Procedures for notifying passengers who booked a 95% passenger vaccinated cruise that their cruise will no longer operate as a 95% passenger vaccinated cruise. (6) The cruise ship operator must submit photographs or videos, no later than seven days after commencing the first voyage with less than 95% of passengers fully vaccinated, showing compliance with indoor mask use and physical distancing, such as signage in elevators, dining table arrangements, and blocking out seats/bar stools.

Similarly, cruise ship operators that have been conducting passenger operations outside of U.S. waters and intend to operate cruise ships with less than 95% of passengers fully vaccinated after repositioning to U.S. waters may, at their discretion, follow the procedures in this paragraph for conducting a modified simulated voyage instead of conducting a full simulated voyage if the following are met: (1) The ship must maintain a percentage of fully vaccinated crew that is greater than or equal to 95%. (2) The ship must have operated

with passengers outside of U.S. waters for at least 60 days before entering U.S. waters. (3) The cruise ship operator must conduct at least one simulation of embarkation screening and testing at the port terminal it intends to use in the U.S.—to include the number of passengers not fully vaccinated expected on the first voyage—unless the ship will be operating at the terminal already in use by the same cruise line/brand for passenger operations. (4) At least 14 days prior to entering U.S. waters, the cruise ship operator must submit the following to CDC: (i) Protocols for how dining and entertainment venues, and recreational activities, including buffets, seated dining, bars (including between bartenders and patrons), theaters, other performance venues, casinos, arcade room, spa services, fitness classes/gymnasiums, muster drills, and other areas where passengers congregate will incorporate mask use, physical distancing, and other public health measures as outlined in technical instructions. (ii) Plans for training crew on procedures for mask use, physical distancing, and other public health measures as outlined in CDC technical instructions. (iii) Protocols for increasing the number of isolation and quarantine cabins and on-board support staff (e.g., administrative personnel, testing personnel, contact tracers, medical personnel) as determined by the cruise ship operator and as needed in the event an outbreak. (iv) Procedures for how crew will identify and distinguish between passengers who are fully vaccinated and passengers who are not fully vaccinated. (v)

Procedures for notifying passengers who booked a 95% vaccinated cruise that their cruise will no longer operate as a 95% vaccinated cruise, if applicable. (vi) An after-action report explaining lessons learned from sailing outside of U.S. waters and from the simulated embarkation screening and testing (if such a simulation was conducted). (vii) The cruise ship operator must submit photographs or videos, no later than seven days after commencing the first voyage with less than 95% of passengers fully vaccinated, showing compliance with indoor mask use and physical distancing, such as signage in elevators, dining table arrangements, and blocking out seats/bar stools.

### Phase 3:

As a condition of applying for a COVID-19 Conditional Sailing Certificate (Phase 3), a cruise ship operator must have successfully conducted a simulated voyage, submitted an Acknowledgement by a Cruise Ship Operator In Lieu of a Simulated Voyage, or – if applicable – completed the specific modified simulated voyage procedures described above. The CDC COVID-19 Conditional Sailing Certificate Application must include: (1) A completed CDC registration/application form that includes the signatures of the cruise ship operator's responsible officials; (2) The name, titles, and contact information for the cruise ship operator's responsible officials; (3) A completed statement of intent stating the name, carrying capacity for passengers and crew, itinerary, ports of call, length of voyage, and expected

onboard or shoreside activities, for the cruise ship that the cruise ship operator intends to have certified for restricted passenger operations; (4) a certification statement signed by the responsible officials attesting that the cruise ship operator has complied and remains in compliance with CDC's requirements for a COVID-19 Response Plan and EDC reporting prior to applying for a COVID-19 Conditional Sailing Certificate; (5) a certification statement signed by the responsible officials attesting that the cruise ship operator has adopted health and safety protocols that meet CDC's standards for mitigating the risk of COVID-19 among passengers and crew onboard the cruise ship that will be commencing restricted passenger operations, and will modify these protocols as needed to protect the public's health as required by CDC technical instructions or orders; (6) a certification statement signed by the responsible officials attesting that the cruise ship operator has sufficient medical and point of care laboratory capabilities and staff on board the cruise ship that will be commencing restricted passenger operations to manage severe COVID-19 cases and outbreaks in exigent circumstances as required by CDC technical instructions or orders; and (7) a certification statement signed by the responsible officials attesting that the cruise ship operator is in compliance with the other requirements contained in this framework for mitigating the risk of COVID-19 on board cruise ships and agrees to continue to comply with these requirements.

These documents must be submitted at least five business days prior to any proposed restricted voyage. If the Certificate is denied, revoked or suspended, a cruise ship operator may submit a written appeal of a denial of its application for a COVID-19 Conditional Sailing Certificate or a revocation or suspension of its COVID-19 Conditional Sailing Certificate.

During restricted voyages, the cruise ships are subject to virtual and in-person inspections by CDC. The cruise ship operator's properties and records must be made available for inspection to allow CDC to ascertain compliance with its requirements. Such properties and records include but are not limited to vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, laboratory test results, and employee and passenger health records. CDC has issued additional technical guidance outlining the specific areas that may be inspected and corresponding recommendations. CDC has provided, and will continue to provide, the technical instructions for each phase as they are released through a non-substantive change request.

CDC requests OMB approval for an estimated 24,146 annual burden hours to respondents and record keepers.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)
Cruise ship	COVID-19	3	1	2400/60



holding company	Response Plan			
Cruise ship physician	Enhanced Data Collection (EDC) During COVID-19 Pandemic Form (Daily)	130	365	20/60
Cruise ship physician	Cruise COVID-19 Case Investigation Worksheet (if necessary)	104	1	30/60
Cruise ship physician	Cruise COVID-19 Contact Investigation Worksheet (if necessary)	24	1	30/60
Cruise ship brand/operator	Approval of Onboard COVID-19 Testing Instrument	60	1	60/60
Cruise ship brand/operator	Mass Crew Testing Requirement	60	1	5/60
Cruise ship brand/operator	Agreement with Health Care Organization with signoff from Local Health Authorities	60	1	600/60
Cruise ship brand/operator	Agreement with Port of Entry with signoff from Local Health Authority	60	1	600/60
Cruise ship brand/operator	Agreement with Housing Facility with signoff from Local Health Authority	60	1	600/60
Cruise ship operator	Request for Approval to Conduct a Simulated Voyage Prior	30	1	600/60

	to Issuance of COVID-19 Conditional Sailing Certificate			
Passenger (3 <sup>rd</sup> party disclosure)	Informed Consent and Medical Certification with no pre-existing conditions for Simulated Voyage	18,000	1	15/60
Cruise ship operator	Remote and In-person Inspections	30	1	120/60
Cruise ship operator	After Action Report, Simulated Voyage	30	1	600/60
Cruise ship operator	COVID-19 Conditional Sailing Certificate Application	60	1	600/60
Cruise ship operator	Remote and In-person Inspections	130	2	120/60

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